

Claims

1. (currently amended) A sustained release tablet, comprising:
a swellable core, the core made from core materials comprising (a) at least one active ingredient, and (b) a mixture of expandable materials, or greater than 25% by weight of an expandable material based upon total core weight, the expandable material or materials expanding upon exposure to an aqueous environment, the core materials defining a belly band comprising the at least one active ingredient; and
an outer rupturable coating surrounding the core, the coating rupturing in a subject's gastrointestinal tract, and comprising a rate release modifying membrane and a water-soluble modifier.
2. (original) The tablet according to claim 1 where the core comprises at least one hydrophilic gum material.
3. (original) The tablet according to claim 1 further comprising an over coating of an active ingredient.
4. (previously presented) The tablet according to claim 1 where at least a portion of the coating ruptures adjacent to or in the belly band upon exposure to an aqueous fluid.
5. (original) The tablet according to claim 4 which produces a support platform for drug delivery.
6. (original) The tablet according to claim 1 where the rate release modifying membrane contains one or more active ingredients.
7. (original) The tablet according to claim 1 comprising pectin.
8. (original) The tablet according to claim 7 where the pectin is low methoxy pectin.

9. (original) The tablet according to claim 1 where the expandable material is an expanding hydrophilic gum or mixture of hydrophilic gums.

10. (original) The tablet according to claim 1 where the rate release modifying membrane is ethyl cellulose or a methacrylate polymer containing modifiers which influence active ingredient release.

11. (original) The tablet according to claim 4 where the belly band is the primary area exposed directly to hydrating fluids by rupture of the rate release modifying membrane.

12. (original) The tablet according to claim 4 where the belly band area is from 0.1 to 1.0 of the tablet height measured at the tallest point.

13. (original) The tablet according to claim 1 where the rate release modifying membrane is over coated or undercoated with an enteric coating material.

14. (original) The tablet according to claim 1 where sustained release of an active ingredient following a lag time is sufficient to provide therapeutically effective active ingredient concentrations when administered in a once- or twice-daily dosing regimen.

15. (previously presented) The tablet according to claim 1 where dissolution of an active ingredient measured *in vitro* in a USP paddle stirring apparatus in appropriate aqueous media at 37°C, substantially corresponds to the following:

- from 0 to 5% of the total active ingredient is released after one hour;
- from 5 to 40% of the total active ingredient is released after four hours;
- from 10 to 80% of the total active ingredient is released after eight hours; and
- not less than 70% of the total active ingredient is released in 24 hours.

16. (previously presented) The tablet according to claim 15 having an active ingredient dissolution lag time, and having an n value of 0.7 or more from time of 10% active ingredient released until time of 75% active ingredient released.

17. (previously presented) The tablet according to claim 16 having an n value of 0.85 or more from time of 10% active ingredient released until time of 85% active ingredient released.

18. (original) The tablet according to claim 1 comprising a mixture of hydrophilic gum polymers, at least one of which is modified by enzymes in the intestinal tract.

19. (original) The tablet according to claim 1 having a drug-delivery lag time of from about 0.5 hours or more and less than or equal to about 6 hours.

20. (original) The tablet according to claim 1 having a drug delivery lag time of from about 1 to about 3 hours.

21. (original) The tablet according to claim 18 where the hydrophilic gum polymer modified by enzymes in the intestinal tract is pectin.

22. (original) The tablet according to claim 1 where the rate release modifying membrane is ethyl cellulose or a methacrylate polymer.

23. (original) The tablet according to claim 4 where the belly band is between 1 and 8 mm thick and the length of the tablet is at least 8 mm.

24. (previously presented) The tablet according to claim 4 where the belly band is equal to or larger than a vertical height of the tablet as measured at a center portion of the tablet.

25. (original) The tablet according to claim 4 where the rate release modifying membrane has been over coated with one or more active ingredients which may or may not exhibit a lag time for active ingredient dissolution.

26. (original) The tablet according to claim 1 where calculated n value for average dissolution results after a lag time is greater than at least 0.70 from time of 10% active ingredient released until time of 75% active ingredient released.

27. (original) The tablet according to claim 1 where calculated n value for average dissolution results after a lag time is greater than at least 0.85 from time of 5% active ingredient released until time of 85% ingredient released.

28. (original) The tablet according to claim 1 where the active ingredient is glipizide.

29. (original) A spray-coated tablet according to claim 1.

30. (previously presented) The tablet according to claim 3 where dissolution of active ingredient from the over coating and dissolution of active ingredient from a coated hydrophilic gum matrix core tablet is approximately zero order in that a calculated n value for average dissolution is greater than 0.70 from time of 10% active ingredient released until time of 75% active ingredient released.

31. (previously presented) The tablet according to claim 3 where dissolution of active ingredient from a coated hydrophilic gum matrix core tablet is approximately zero order, independent of active ingredient release from the over coating, in that a calculated n value for average dissolution from the coated core is greater than 0.70 from time of 10% active ingredient released until time of 75% active ingredient released.

32. (previously presented) The tablet according to claim 3 where dissolution of the active ingredient from the over coating plus dissolution of active ingredient from a coated hydrophilic gum matrix core tablet is approximately zero order in that a calculated n value for average dissolution result is greater than 0.85 from time of 5% active ingredient released until time of 85% active ingredient released.

33. (previously presented) The tablet according to claim 3 where dissolution of the active ingredient from a coated core tablet is approximately zero order, independent of active ingredient release from the overcoating, in that a calculated n value for average dissolution result from the coated core is greater than 0.85 from time of 5% active ingredient released until time of 85% active ingredient released.

34. (previously presented) The tablet according to claim 3 wherein there is a burst dissolution of active ingredient(s) from the over coating, and then a calculated n value for average dissolution results for at least one active ingredient released from a coated core tablet after a lag time is greater than at least 0.70 from time of 10% release of the active ingredient in the core tablet is released until time of 75% of the active ingredient in the core tablet is released.

Claims 35-57 (canceled)

35 ~~58~~. (previously presented) The tablet of claim 1 where, during hydration with aqueous fluids, the swellable core swells and ruptures the rate controlling membrane which breaks away from part of the tablet and exposes portions of the core tablet, and remains attached to portions of the tablet providing a support platform for at least two hours after initial breaking of the polymer release rate controlling film.

36 ~~59~~. (previously presented) The tablet of claim 33 where, during hydration with aqueous fluids, the swellable core swells and ruptures the rate controlling membrane which breaks away from part of the tablet and exposes portions of the hydrophilic gum polymer core tablet, and remains attached to portions of the tablet providing a support platform for at least two hours after initial breaking of the polymer release rate controlling film occurs.

Claims 60-72 (canceled)

37 ~~73~~. (currently amended) A method for administering an active ingredient, comprising: providing a tablet comprising a core having an active ingredient and an expandable material ~~which~~ that expands upon exposure to aqueous environment, the core surrounded by an

outer rate release modifying membrane ~~which that~~ ruptures in a subject's gastrointestinal tract,
the tablet having a belly band comprising the active ingredient upon exposure to aqueous
environment; and
administering the tablet to ~~a patient~~ the subject.

Claims 74-78 (canceled)

38 79. (currently amended) A method for administering an active ingredient, comprising:
providing a tablet, the tablet comprising [(a)] a core comprising an active ingredient and
an expandable material ~~which that~~ expands upon exposure to an aqueous environment, ~~and (b)~~ an
outer rupturable rate release modifying membrane; that ruptures in a subject's gastrointestinal
tract, the tablet providing active ingredient release over at least a 16-hour period, and a belly
band comprising the active ingredient; and
administering the tablet to ~~a patient~~ the subject.

39 80. (original) The method according to claim 79 ³⁸ where the expandable material is
enzymatically modifiable.

Claim 81 (canceled)

40 82. (original) The tablet according to claim 1 where the outer rupturable coating
includes a water insoluble modifier.

41 83. (currently amended) A tablet, comprising:
a core having [(a)] at least one active ingredient, ~~and (b)~~ a mixture of expandable
materials, or greater than 25% by weight of an expandable material based upon total core weight,
the expandable material or materials expanding upon exposure to an aqueous environment, and a
belly band comprising the at least one active ingredient; and

an outer rupturable coating surrounding the core that ruptures in a subject's gastrointestinal tract, the coating comprising a rate release modifying membrane and a film modifier.

412 84. (original) The tablet according to claim ⁶¹¹83 where the rate release modifying membrane is ethyl cellulose or a methacrylate polymer containing modifiers which influence active ingredient release.

43 85. (currently amended) A method for administering an active ingredient, comprising: providing a tablet which exhibits a lag time for active ingredient dissolution from a core, the tablet comprising a core having an expandable material which expands upon exposure to an aqueous environment, at least one active ingredient, a belly band comprising the at least one active ingredient and an outer rupturable coating surrounding the core comprising a rate release modifying membrane and a film modifier; and

administering the tablet to a ~~patient~~ subject, the tablet thereafter undergoing hydration so that, during hydration of the tablet, the core swells and ruptures the rate release modifying membrane in a subject's gastrointestinal tract, which breaks away from part of the tablet and exposed portions of the core, and remains attached to portions of the tablet providing a support platform for at least two hours when tested *in vitro* after initial rupture of the rate release modifying ~~polymer~~ membrane occurs.

44 86. (currently amended) The tablet according to ~~claims~~ claim 15 where from 20 to 80% of the total active ingredient is released after eight hours.

45 87. (original) The tablet according to claim 15 where not less than 80% of the total active ingredient is released in 24 hours.

46 88. (currently amended) A tablet, comprising:
a core having [(a)] at least one active ingredient, ~~and (b)~~ a mixture of expandable materials, or greater than 25% by weight of an expandable material based upon total core weight,

the expandable material or materials expanding upon exposure to an aqueous environment, and a belly band comprising the at least one active ingredient;

an outer rupturable coating that ruptures in a subject's gastrointestinal tract; and

an over coating comprising at least one active ingredient.

47 89. (currently amended) A tablet, comprising:

a core having ~~[[a]]~~ at least one active ingredient, ~~and (b)~~ a mixture of expandable materials, or greater than 25% by weight of an expandable material based upon total core weight, the expandable material or materials expanding upon exposure to an aqueous environment~~[[a]]~~, and a belly band comprising the at least one active ingredient; and

an outer rupturable coating that ruptures in a subject's gastrointestinal tract.

48 90. (currently amended) A tablet, comprising a core having ~~[[a]]~~ at least one active ingredient, ~~and (b)~~ a mixture of expandable materials, or greater than 25% by weight of an expandable material based upon total core weight, the expandable material or materials expanding upon exposure to an aqueous environment, and a belly band comprising the at least one active ingredient, where dissolution of the active ingredient is approximately zero order following an active ingredient dissolution lag time of from about 0.5 hour to about 6 hours.